JAN 19 2006

K052004

## 510(k) SUMMARY

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| **Submitter's Information** | VasCon LLC<br>9344 NW 13 Street<br>Miami, Florida 33172 USA<br>Telephone: 1-305-477-2406<br>Contact: Stephen F. Vadas, Ph.D. |
| **Preparation Date** | July 6, 2005 |
| **Name of Device** | Common Name: Guiding Catheter<br>Classification Name: Percutaneous Catheter<br>Trade Name: VasCon NeuroPath™ Guiding Catheter |
| **Predicate Devices** | Cordis Guiding Catheter (ENVOY® series)<br>VasCon Guiding Catheter (Polaris™) |
| **Intended Use** | VasCon NeuroPath™ Guiding Catheter is intended for use in the coronary, peripheral, and neurovasculature for intravascular introduction of interventional/diagnostic devices. |
| **Device Description and Summary of Technological Characteristics** | The VasCon NeuroPath™ Guiding Catheter is a single lumen catheter, incorporating a PEBAX® body reinforced with a stainless steel wire braid. The intermediate segment is also PEBAX® with a stainless steel coil to reduce kinking and to promote improved torque response. The tip is composed of radiopaque 35D PEBAX® to reduce potential vessel injury. They are available in 5Fr and 6Fr, 90 and 100 cm in length, and in a variety of shapes. The technological characteristics are equivalent to the predicate devices. |
| **Testing Summary** | Mechanical laboratory testing has been performed on the VasCon NeuroPath™ Guiding Catheter to assure compliance to the specifications. In addition, testing has been performed on the materials to assure biocompatibility. |
| **Conclusions** | The non-clinical tests as discussed above demonstrate that, like the predicate devices, the VasCon NeuroPath™ Guiding Catheter is safe and effective for its intended use. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2006

VasCon LLC
c/o Stephen F. Vadas, Ph.D.
Vice President, Product Assurance & Regulatory Affairs
9344 N.W. 13 Street, Suite 200
Miami, FL 33172

Re: K052004
VasCon NeuroPath™ Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II
Product Code: DQY
Dated: December 27, 2005
Received: December 29, 2005

Dear Dr. Vadas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**INDICATIONS FOR USE**

**510(k) Number** (if known): K052004

**Device Name:** VasCon NeuroPath™ Guiding Catheter

**Indications for Use:**

VasCon NeuroPath™ Guiding Catheter is intended for use in the coronary, peripheral, and neurovasculature for intravascular introduction of interventional/diagnostic devices.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052004